Region 4 U.S. Environmental Protection Agency Science and Ecosystem Support Division Athens, Georgia

OPERATING PROCEDURE

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Auth	or			
Name: Liza Montalvo Title: Environmental Engineer				
Signature: Lall Date	e: 9/7//o			
Approvals				
Name: Archie Lee				
Title: Chief, Enforcement and Investigations Branch				
Signature Date: 8/7/2018				
Name: Bill Cosgrove				
Title: Chief, Ecological Assessment Branch				
Signature: July Date: 9/7/10 Name: Liza Montalyo				
Name: Liza Montalvo				
Title: Field Quality Manager, Science and Ecosy	ystem Support Division			
Signature: Italian Dat	re: 9/7/10			

Revision History

This table shows changes to this controlled document over time. The most recent version is presented in the top row of the table. Previous versions of the document are maintained by the SESD Document Control Coordinator.

History	Effective Date
SESDPROC-002-R5, <i>Control of Records</i> , replaces, SESDPROC-002-R4	September 8, 2010
Title Page: Changed the following: Author from Laura Ackerman to Liza Montalvo; Enforcement and Investigations Branch Chief from Antonio Quinones to Archie Lee; and, Field Quality Manager from Laura Ackerman to Liza Montalvo.	
Revision History: Added explanation for the revision history table.	
Section 1.3: Omitted reference to the H: drive.	
Section 2.2: Deleted "or signing" from the first sentence of the second paragraph.	
Section 3.6: Changed retention period from 2 to 4 years.	
Section 4.1: Added requirements for the origination of project files for projects that do not require a QAPP.	
SESDPROC-002-R4, Control of Records, replaces SESDPROC-002-R3	February 11, 2008
Section 1.1: Replaced former text with current text.	
Section 1.2: Replaced first sentence of first paragraph with current text. Deleted last sentence of second paragraph.	
Section 1.3: Changed Field Quality Manager to Document Control Coordinator.	
Section 1.4.3: Expanded definition	
Section 1.4.4: Added "calculations".	
Section 2.1: Added "technical" to first sentence of third paragraph. Added second and third sentences to third paragraph.	
Section 2.2: Added second paragraph.	
Section 3: Added all information and subsections.	

Section 4: Most information was retained and reorganized so that subsections coincide with Section 3.	
Section 4.2: New information.	
Section 4.3 and 4.4: New section titles.	
Section 4.6: Added "Filing" to title. Added second paragraph.	000
Section 4.7: New information.	
Section 4.8: New title. Added last sentence.	
Section 4.10: Deleted information about Privileged Information, Grand Jury Rule 6(e) Confidential Information, and National Security Information.	
SESDPROC-002-R3, Control of Records, replaces SESDPROC-002-R2	November 1, 2007
This revision reflects the following changes:	PLEASING
General: Corrected any typographical, grammatical, and/or editorial errors. Updated referenced procedures due to changes in title names and/or to reflect most recent version.	
Title Page: Changed title for Antonio Quinones from Environmental Investigation Branch to Enforcement and Investigations Branch.	ALCOHOLOGY CONTRACTOR
Section 1.5: Alphabetized. Added the following references: EPA National Security Information Handbook, Project File Checklist, and Region 4 Guidance for Handling Confidential Business Information.	
SESDPROC-002-R2, Control of Records, Replaces SESDPROC-002-R1	October 1, 2007
This revision reflects the following changes:	
General: The revision history in SESDPROC-002-R1 was incorporated using a hyperlink. In SESDPROC-002-R2, the hyperlink was removed and the revision history was incorporated into the document.	TO COMMITTEE OF THE PROPERTY O
Section 1.4.3: Revised definition of a quality record.	Manufacture (
SESDPROC-002-R1, Control of Records, Replaces SESDPROC-002-R0	August 10, 2007
This revision reflects the following changes:	BEARACHTERSALANA
General: Deleted all references to the SOSA. All components of the SESD Procedure for Project File Management, SESDPROC-004-R0, were incorporated into this procedure. The Project File Management Procedure has been archived and will no longer be used.	

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Cover Page: Author was changed from Sharon Matthews to Laura Ackerman due to extensive re-writes by Laura Ackerman. Section 1.1: Reworded first sentence. Deleted second sentence. Section 1.2: Combined first and second sentences in first paragraph. Included third paragraph with first paragraph. Second paragraph was completely revised. Section 1.3: Updated to reflect that the official copy of the procedure resides on the H: drive rather than with the FQM. Section 1.4: Added EPAs definition of a record in Section 1.4.1. Added SESD Field Branches definition of a record in Section 1.4.2. Added definition of a quality record in Section 1.4.3. Moved definition of a Technical Record from Section 1.4.8 to Section 1.4.4 and revised definition. Moved definition of a Project File from Section 1.4.4 to Section 1.4.6 and revised definition. Removed definitions of an Administrative Record, Non-Record Materials, Personal Papers, and Field Measurement Records. Section 1.5: Removed references to: 1) SESD SOSA and 2) US EPA Region 4 Environmental Investigations Standard Operating Procedure and Quality Assurance Manual, November 2001. Added references to: 1) EPA Records Management Policy and 2) EPA Records Management manual. Section 2.1: Completely revised section. Section 2.2: Added second sentence. Section 2.3: Section was completely rewritten. Defined records in terms of ISO 17025. Section 2.4: Information was revised and transferred to Sections 3 and 4. Section 3: Information was revised and incorporated into Section 4.

February 5, 2007

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SESDPROC-002-R0, Control of Records, Original Issue

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1 Control of Records

1.1 Purpose

This procedure describes the process the field branches use to identify, collect, index, access, file, store, maintain, protect, back-up and dispose quality and technical records.

1.2 Scope/Application

This procedure applies to all quality and technical records generated by the field branches. This procedure does not apply to records obtained from other organizations during field investigations involving environmental data collection. Those records should be handled as evidence according to the SESD Operating Procedure for Sample and Evidence Management, SESDPROC-005.

It is the responsibility of SESD field investigators to create records sufficient to document their business activities, and not to destroy or remove records except in accordance with approved Agency records schedules.

1.3 Documentation/Verification

This procedure was prepared by persons deemed technically competent by SESD management, based on their knowledge, skills and abilities and have been tested in practice and reviewed in print by a subject matter expert. The official copy of this procedure resides on the SESD Local Area Network (LAN). The Document Control Coordinator (DCC) is responsible for ensuring the most recent version of the procedure is placed on the LAN and for maintaining records of review conducted prior to its issuance.

1.4 Definitions

1.4.1 Records (EPA)

EPA defines records as all books, papers, maps, photographs, machine-readable materials or other documentary materials, regardless of physical form or characteristic, made or received by an agency of the U.S. Government under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, function, policies, decisions, procedure, operation, or other activities of the Government or because of the informational value of the data in them (44 U.S. C 3101, Definition of Records).

1.4.2 Records (SESD Field Branches)

For the requirements of ISO 17025, the SESD field branches define a record as objective evidence of actions taken or observations made while implementing the SESD Field Quality System. This includes both hard-copy and electronic records.

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1.4.3 Quality Records

For the requirements of ISO 17025, the SESD field branches define quality records as audit reports, management reviews, corrective action requests, preventive action requests, quality improvements, personnel records (including testimony evaluations, training records, and competency evaluations and proficiency tests), and equipment records.

Technical Records 1.4.4

ISO 17025 defines technical records as original observations, calculations, derived data, ancillary information needed to establish an audit trail, calibration records, staff records and copies of test reports.

1.4.5 Records Management

The planning, controlling, directing, organizing, training, promoting, and other managerial activities involved with respect to records creation, records maintenance and use, and records disposition in order to achieve adequate and proper documentation of the policies and transactions of the Federal Government and effective and economical management of agency operations.

1.4.6 Project File

For the purposes of ISO 17025 compliance, the official file is maintained in the SESD Central Records Room. These files include a variety of documents and records that support SESD field investigations and document reviews.

1.4.7 Records Schedules

Documents that provide continuous authority to dispose of recurring series or systems of records, or to transfer them to Regional Records Centers. (See SESD Records Management Standard Operating Procedures, Current Version)

1.5 References

EPA National Security Information Handbook, October 1997

EPA Records Management Manual, Current Version, www.epa.gov/records/policy/manual

EPA Records Management Policy, Current Version, www.epa.gov/records/policy/2161/ index.htm

EPA Region 4 Guidance on Handling Confidential Business Information, October 2001

Project File Checklist, SESDFORM-016, Most Recent Version

SESD Operating Procedure for Field Measurement Uncertainty, SESDPROC-014, Most Recent Version

SESD Operating Procedure for Sample and Evidence Management, SESDPROC-005, Most Recent Version

SESD Records Management Standard Operating Procedures, Current Version

2 Procedure

2.1 General

The Federal Records Act of 1950, as amended, requires all federal agencies to make and preserve records containing adequate and proper documentation of their organization, function, policies, decisions, procedures, and essential transactions. These records are public property and must be managed according to applicable laws and regulations. The Federal Records Act also requires agencies to establish a records management program, defined as a planned, coordinated set of policies, procedures, and activities needed to manage its recorded information.

Based on the Federal Records Act, EPA established the Records Management Policy. According to the Policy, each regional office within EPA is required to establish and maintain a records management program. Within EPA, Region 4, each organizational element is assigned record keeping responsibility in accordance with its functional responsibilities and duties. Therefore, SESD has established records management procedures that comply with federal, agency, and regional requirements (SESD Records Management Standard Operating Procedures).

The SESD field branches manage their technical records in accordance with the SESD Records Management Standard Operating Procedures and ISO 17025 requirements. The SESD Records Management Standard Operating Procedures do not address quality system records. Therefore, quality system records are managed in accordance with ISO 17025 requirements.

All records included in the scope of EPA's definition of a record in Section 1.4.1 will be managed in accordance with the EPA Records Management Policy.

Quality records and technical records are included within the scope of the SESD field branches' definition of records in Section 1.4.2 and will be managed in accordance with this procedure.

2.2 Creating Records

Records must be created to adequately document activities for which field investigators are responsible. Records of field measurements will contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty of field measurements and to enable the measurement to be repeated under conditions as close as possible to the original. (See the SESD Operating Procedure for Field Measurement Uncertainty, SESDPROC-014) Records will be legible and clearly and permanently identify the person making the record. Records should also include the date of creation and the document title.

When mistakes occur in records, each mistake will be corrected by drawing a line through the mistake and **initialing and dating** the lined-through entry. Under no circumstances should the mistake be erased, made illegible or obscured so that it cannot be read.

3 Quality Records

3.1 Identification

Quality records are identified with a descriptive title that clearly labels the record.

3.2 Collection

The individuals who are responsible for collecting quality records are identified in the specific operating procedures. In general, it is the user of the records or the Field Quality Manager.

3.3 Indexing

Each record is assigned a unique name, number or alphanumeric identification to distinguish it from other records.

3.4 Access

Quality records are stored either at the SESD laboratory or at the Field Equipment Center and are readily accessible to individuals requiring information contained in the records. Following is a list of quality records and the individual responsible for their maintenance:

Record	Responsible Individual
Training Records	Field Quality Manager
Purchasing Records	Branch Field Equipment Managers
Quality System Plans, Procedures, and	Document Control Coordinator
Guidance Documents	
Internal Audits	Field Quality Manager
Corrective Actions	Field Quality Manager
Quality Improvements/Preventive Actions	Field Quality Manager
Competency Evaluations/Proficiency Tests	Field Quality Manager
Supply Verification Results	Branch Field Equipment Managers/EIB
Supply verification resource	QAO ·
Management Reviews	Field Quality Manager
Field Measurement Uncertainty	EIB Quality Assurance Officer
Testimony Evaluations	Field Branches Management, Field Quality
16stimony Dvardations	Manager
Nonconforming Work	Field Quality Manager
Complaints	Field Quality Manager
	Branch Field Equipment Managers
Equipment	

3.5 Filing and Maintenance

Quality system records are filed and maintained at either the SESD laboratory or at the Field Equipment Center by the individuals responsible for the records. Electronic quality records are stored on the SESD local area network (LAN). The LAN is backed up to magnetic tapes Monday through Saturday evenings using a redundant network backup system. One backup is conducted remotely from the EPA Office of Research and Development computer center in Athens, Georgia and another locally from the SESD computer center. After successful backups, the tapes located at SESD are placed in a fire-proof media safe and a copy of the Friday evening backup is rotated to the Atlanta EPA office for offsite storage.

3.6 Retention

Quality records are kept for a minimum of four years and may be retained longer if necessary or convenient.

3.7 Disposition

Records are disposed when the retention time has been exceeded. Disposition may be to discard or destroy the records or to put them in long-term storage. The Field Quality Manager is responsible for disposition of the field branches quality records.

3.8 Storage

After the retention time, if long-term storage is required, quality records will be placed in the SESD Central Records Room in a dedicated location that will be determined by the contractor responsible for the Records Room.

4.1 Project File Management

Project files are the mechanism used to document, control and manage technical records created or obtained during field investigations. Official copies of all technical records will be in hard copy format. The project file will be originated by the Section Chief or their designee when the Quality Assurance Project Plan (QAPP) or other written communication is transmitted to the customer via official correspondence. For projects that do not require a QAPP such as compliance evaluation inspections, performance audit inspections and technical systems audits, the project file will be originated with a copy of the Region 4 Laboratory Information Management System (R4LIMS) record of the project.

4.2 Identification

Each project file is filed by state, then alphabetically by project name.

4.3 Collection

In general, project files should contain the records required to support reported results, conclusions, and interpretations such that in the absence of the project participants, other personnel, as assigned by SESD management, could evaluate what had been performed and interpret the data. All SESD-generated records which are included in the project file will include the following: 1) a unique project identifier (project identification number) on each page, 2) page numbers indicating the total number of pages (page x of y), 3) clear identification of the project leader and any other responsible individuals, as appropriate, and 4) all dates relevant to the project. Non-SESD-generated records in project files (e.g., background information) will be labeled with the project identification number on each page such that if the records are separated from the project file, they could be easily associated with the correct file.

Once the final report has been issued for a project, the project leader must compile all of the applicable information listed on the Project File Checklist (SESDFORM-016), sign and date the form and forward it to their Section Chief. The Section Chief will review the Project File Checklist to ensure the information is complete and sign and date the Checklist form. The Section Chief or their designee will then deliver the information to the Central Records Room for inclusion in the project file. The project file is complete at this point.

4.4 Indexing

Each branch project file is color-coded. Enforcement and Investigation Branch project files will be maintained in yellow expandable file folders. Ecological Assessment Branch project files will be maintained in green expandable file folders. Each folder will contain two outside labels which will state the EPA series number, project name, project identification number, city and state. Criminal investigation project files will be shelved the same as other project files within the Division.

4.5 Access

Technical records are stored in the Central Records Room which is a controlled access area that provides centralized storage, management, retrieval, and final disposition for project files by utilizing:

- Non-office space storage
- Ready retrievability in a secure area to help prevent damage, deterioration, or loss
- Centralized, computerized tracking and circulation
- Uniform scheduling, destruction, and archiving according to the U.S. EPA National Records Management Program and the Federal Records Act (44 U.S.C. 31)

The Central Records Room is managed by contract personnel who are available to assist in locating project files and to see that the files are signed out appropriately. In the event the contractor is unavailable, the Central Records Room is locked. Any branch secretary can obtain the Central Records Room key from the guard's desk or a branch chief. The secretary is required to stay with individuals while they obtain technical records. A sign-out sheet is maintained on the desk in the Central Records Room to log-out records in the absence of contract personnel.

There is no public access to the Central Records Room. Files are made available to the public through the Freedom of Information Act.

4.6 Filing and Maintenance

SESD maintains its project files in the Central Records Room, B102 at the SESD laboratory. The Central Records Room is staffed by a contractor. The contract is managed by the Regional Records Manager, US-EPA, Region 4, Atlanta, Georgia.

For field measurement data collected and stored exclusively as electronic records, the original, raw data will be backed up to another media such as a laptop computer, jump-drive, or CD prior to demobilization from the study. The location of the backup will be noted in the field logbook. Upon return to the laboratory, the original, raw data will be copied onto a non-rewritable CD and the CD will be included in the SESD project file. At a minimum, the CD should be labeled with the data identification, the project name, the project identification number, and the date.

4.7 Retention

Technical records are retained according to EPA records schedules. The most current EPA records schedules are available at http://epa.gov/records/policy/schedule/index.htm.

4.8 Disposition

Project files will be disposed of according to EPA records schedules. EPA records schedules identify records as either temporary or permanent, and provide specific, mandatory instructions for the disposition of the records when they are no longer needed for Agency business.

Disposition schedules for the records generated by the field branches can be found at http://epa.gov/records/policy/schedule/function.htm.

4.9 Storage

Due to the limited capacity of the Central Records Room, selected project files may be transferred to the Federal Records Center in Atlanta, Georgia. SESD maintains custody of the files stored at the Federal Records Center and access is strictly controlled. No individual may access SESD records at the Federal Records Center without authorization from the SESD Records Information Manager or their designee.

Confidential Business Information 4.10

Only individuals who have completed confidential business information (CBI) training are allowed to receive CBI material while in the field. If CBI is received while in the field, it should be secured until its return to SESD, then submitted to contract personnel in the SESD Central Records Room for labeling and processing. Authorization for access to this material is obtained by acknowledging, in writing, awareness of the agreement and the penalties for willful disclosure of CBI.

It is the Region 4 policy that CBI will not be permanently maintained in SESD files. CBI material, however, may be retained by SESD field investigators for the duration of the project but must be secured according to procedures outlined in the Region 4 guidance document Handling Confidential Business Information, October 2001. Following completion of the project, CBI material will be maintained by the Region 4 EPA program office requesting the investigation.